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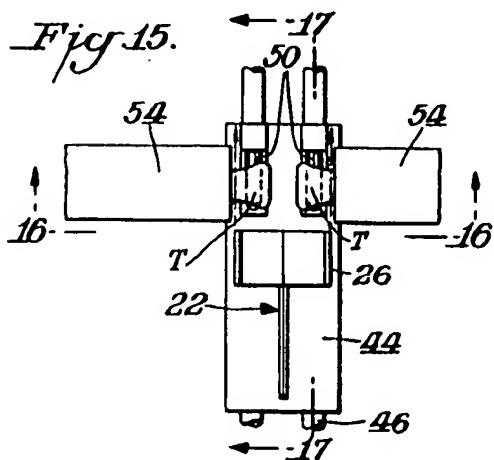
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㉔ Total containment welding of plastic tubes.

㉕ A pair of hollow plastic tubes (T) are welded together by mounting each tube in the clamp jaws of a holder (54) in a bent condition to form the U-shape. A structural element (50) is utilized to create a space between the bight of the U-shape and the holder. The bent tubes are disposed toward each other. A tube section separating member (26) is moved into contact with the bent tubes and through the space between each bight and its holder to create a set of two tube sections from each bent tube. A tube section from one set is aligned with a tube section from the other set and the aligned sections are welded together. The structural element may be a weld seam resulting from a prior welding.



EP 0 583 582 A1

### Cross-Reference to Related Applications

This application is a continuation-in-part of application Serial No. 764,249 filed September 23, 1991, application Serial No. 682,977 filed April 10, 1991 and application Serial No. 604,979 filed October 29, 1990.

### Background of the Invention

The present invention is directed to the total containment welding of plastic tubes. Various prior art exists disclosing different approaches for welding plastic tubes together. The general approach which had been followed by the prior art was to place two tubes across a pair of holders and then cut through the tubes to form two sets of aligned tube sections. One of the sets would then be moved to realign a section from one set with a section from the other set. The realigned tubes would then be welded together.

U.S. Patent No. 4,753,697 discloses a variation of the prior general approach. In U.S. Patent 4,753,697 Figures 17-20 illustrate a technique wherein each tube in a pair of tubes is folded back toward itself to create a U-shape. A heated wafer is positioned in the space between the bent tubes. The bent tubes are then moved toward each other against the stationary heated wafer. The heated wafer melts sufficiently through the tubes to create four tube sections. The heated wafer is then removed from between the four tube sections and the aligned tube sections are welded together.

The above parent applications describe an improvement over the techniques illustrated in Figures 17-20 of U.S. Patent No. 4,753,697. This improvement involves a melt/wipe process wherein there is simultaneous movement of the heated wafer through the gap between the tubes as the tubes are moved toward each other. Thus, the moving wafer melts the tubes as it wipes across them.

Parent applications Serial No. 604,979 and Serial No. 682,977 relate to the techniques wherein each tube is folded toward itself to form a U-shape. Parent application Serial No. 764,249 discloses a variation of those techniques wherein there is no bending of the tube. The reason for avoiding the tube bending is the concern that in the inner portion of the bight where the tubes are bent, bacteria will exist which will not be killed during the melt/wipe process. By avoiding a bending of the tubes there is no inner bight portion where bacteria can survive.

### Summary of the Invention

An object of this invention is to provide techniques for the sterile or total containment welding

of plastic tubes.

A further object of this invention is to provide such techniques which are particularly adaptable for use with the melt/wipe system.

5 A still further object of this invention is to provide a total containment welding of plastic tubes which utilizes bent tubes while effectively killing any bacteria that might otherwise be at the inner bight portion of the bent tubes.

10 In accordance with this invention, each tube is mounted in the clamp jaws of a holder bent toward itself to form a U-shape. A structural element is utilized to create a space between the bight of the U-shape and the holder. A tube section separating member which is preferably a heater wafer is moved into contact with the bent tubes and through the space between each bight and its holder to create a set of two tube sections from each bent tube. A tube section from one set is aligned with a tube section from the other set and the aligned tube sections are welded together.

15 The structural element may be the weld seam on the tube resulting from a prior welding of two tube segments welded together to form the tube. 25 The weld seam would be disposed against the holder near the bight and act as a lever to pivot the bight away from the holder. Where the tube has no weld seam, the structural element may be a rod around which the tube is bent and then the rod is removed.

20 In a preferred practice of the invention the heated wafer includes a pair of offset parallel melt members which are offset from the central portion by a distance to dispose each melt member at the space between the holder and the bight. Each melt member may include an outwardly extending projection or sweep for clearing out any debris during the melt operation.

30 In accordance with a further embodiment of the invention the wafer has a pair of wing sections which are dimensioned to extend across the bight portion and into the space near the holder.

### The Drawings

35 45 Figure 1 illustrates a plastic tube which would be utilized with a second similar plastic tube in one practice of this invention; Figure 2 is a cross-sectional view in elevation of a total containment welding system in accordance with this invention for welding tubes such as shown in Figure 1; Figure 3 is a perspective view of a tube section separating member in the form of a heated wafer which is usable in the practice of this invention; Figure 4 is a perspective view of an alternate view of tube section separating member;

Figure 5 is a plan view showing an initial step in the method for practicing the invention using the wafer of Figure 3 with the tubes and holders of Figure 2; 5 Figure 6 is an elevation view in section of the Figure 5 step in the sequence of practicing the invention; 10 Figures 7-8 are elevation views in section showing still further steps in the sequence of practicing the invention; 15 Figure 9 is a plan view similar to Figure 5 showing use of the wafer of Figure 4 in the practice of this invention; Figure 10 is a cross-sectional view taken through Figure 9 along the line 10-10; 20 Figure 11 is a view similar to Figure 10 showing a further step in the practice of this invention; Figure 12 is a plan view showing a further alternative practice of this invention; 25 Figure 13 is a cross-sectional view taken through Figure 12 along the line 13-13; Figure 14 is a cross-sectional view in elevation showing a further step in the practice of the invention shown in Figures 12-13; 30 Figure 15 is a top plan view of a total containment welding system in accordance with a further alternative practice of this invention; and Figures 16 and 17 are cross-sectional views taken through Figure 15 along the lines 16-16 and 17-17, respectively.

#### Detailed Description

The various parent applications disclose techniques for effectively welding plastic tubes together. The details of those parent applications are incorporated herein by reference thereto. Parent application Serial No. 604,879 and parent application Serial No. 682,977 relate to techniques utilizing a melt/wipe process wherein four tube sections are formed by melt/wiping across two bent tubes. Parent application Serial No. 764,249 discloses a variation of the melt/wipe process which avoids the bending of the tubes and rather operates while the tubes are in a straight unbent position.

There are circumstances where the bending of tubes is desirable. For example, the bending of tubes gently expresses live cells away from the weld site. This is particularly important for a) blood and blood component protocols, b) where all liquid should be removed from the weld site to make a weld without encountering the liquid heat sink, c) a process which is totally contained in that nothing enters and nothing leaves, d) various practices of the melt/wipe process, e) a process which avoids leakages or spills by clamping the tube in the area of the bend, f) for use in all thermal plastic tube compositions, g) where it is desired to have dis-

carded stub ends which can be retained for a sample record of infused fluids, and h) where the stub ends are desired for providing a quantitative analysis for therapy of a patient or process.

The present invention, in general, involves techniques for forming an open area in the bight portion of the U-shaped bend where the U-shaped bend extends outwardly beyond the holders. The tubes are then severed into sections by a tube section separating member which passes through the open space. In the preferred practice of the invention the melt/wipe system is used which incorporates a heated wafer as the tube section separating member. In the preferred practice of the invention the two sets of bent tubes are automatically aligned with each other when each tube is separated into two tube sections by aligning the bent tubes before separation. Thus, each tube section is aligned with a corresponding tube section from the other tube. The invention, however may be practiced in other manners including the use of a cutting instrument as the tube section separating member rather than a heated wafer. Additionally, the bent tubes need not be initially aligned, but rather the alignment of the two sections to be joined together may be accomplished by a subsequent displacement by one or both sections after the separation has taken place as is done in the prior art.

Figures 1-3 and 5-8 illustrate one practice of the invention. As shown therein use is made of the fact that a tube T is in the form of a tube which had originally been two tube segments welded together to form a weld seam W having an enlarged diameter flange with respect to the diameter of the tube T. The weld seam or flange W can be shaped to control the amount of flange for subsequent welding by making small pockets in the clamp faces.

As shown in Figure 2 an assembly 10 is provided for accomplishing the total containment welding of plastic tubes T<sub>1</sub> and T<sub>2</sub>. As shown therein the assembly 10 includes a pair of holders 12,14 each of which is provided with a pair of clamp jaws 16,18. An intermediate spacer bar 20 is located between the clamp jaws. In practice a tube would be placed in a groove in its holder and bent around spacer 20. The tube would be pulled rearwardly until the flange or weld seam W is disposed in contact with the outer surface of spacer 20. This technique for the proper location of weld seam W being achieved by placing the tube a groove and pulling the tube until the weld seam contacts the spacer 20 is schematically illustrated in Figure 1. The tube would then be bent over spacer 20 and the clamp jaws 16,18 would be moved toward each other to create a flattened portion of the tube at its U-shaped bend with any liquid L being squeezed away from and out of the flattened portion as

shown in cross-section in Figure 2. This assures trapping bacteria and cells and forcing the cells out of the bent section where the tube is flattened by the clamp jaws. The weld seam W acts as a lever or pivot member to assure that a space S is created at the bight portion of the bent tube which extends outwardly beyond holder 12 or 14. The holders are then moved toward each other until the bent tubes barely touch as shown in Figure 5.

In the practice of this invention utilizing the melt/wipe technique, a heated wafer is used as the tube section separating member. The wafer may take various forms including the various forms illustrated in the parent applications. Figure 3 shows a form of wafer 22 which includes a substantially flat main portion 24 and has a pair of parallel offset portions 26 which form legs of a U at the upstream or lead end of the wafer 22 to form a melting section. The legs 26 have outward bends or bulges 28 which function as sweep elements. In practice, wafer 22 would be moved toward the bent tubes as the tubes are moving toward each other. The spacing between legs 26, 26 is such that the legs are spaced by the distance between the open spaces S,S when the legs contact the bent tubes. Because wafer 22 is a heater element the legs melt through the bent tubes and wipe the melted plastic away in the melt/wipe technique described in the parent applications. Wafer 22 continues to move in its tube section separating direction simultaneously with the holders moving toward each other to maintain proper contact of legs 26 with the tube ends. Figure 5, for example, illustrates the initial phase of the tube section separation. Figure 6 is an elevation view of Figure 5 and shows the legs partially through each bent tube as they are melting through the bent tubes.

Figure 7 illustrates the next sequence of operation after legs 26,26 have passed through the bent tubes and the resulting tube sections have been urged into contact with the main flat portion of wafer 22. As shown therein a set of two tube sections is formed from each bent tube with a section of each set being aligned with a corresponding section of the other set. By maintaining the four tube sections in contact with the flat portion 24 of heated wafer 22 the ends of the tube sections are maintained in a melted condition capable of being welded together.

Figure 8 shows the tube sections after the trailing end of wafer 22 has completely passed through the tubes and when the holders have urged the melted ends of each tube section into contact with a corresponding aligned tube section to form weld seams W, which joins each pair of tube sections together. One of the joined pairs of tube sections could be used, for example, to connect the main portions of the tubes while the other

pair of joined tube sections could produce a stub ends which could be disposed of or could be used for other purposes as previously described.

During the tube section separation by means of wafer 22 debris might result in the exposed interior of each tube section. Sweep member 28 functions to penetrate the interior and remove any such debris which would otherwise exist between the tubes.

Any suitable dimensions may be used for the U-shaped portions of wafer 22. For example, each leg 26 may be 6 mm high with sweep member 28 located centrally 3 mm from each end and projecting outwardly 1 mm. Sweep member 26 preferably has a thickness of 0.5 mm. The legs 26 would be spaced, for example, 5 mm apart. Wafer 22 itself would have a length of 28 mm and a height of 20 mm.

A further advantage of wafer 22 is that the U-shaped separating sections form a collection channel for melted material at the bight of each bent tube.

Once the pairs of tube sections have been joined together it is possible to open communication between the resultant tube by simply popping open the seal under finger pressure.

Figure 4 illustrates an alternative form of wafer 30. As shown therein wafer 30 includes a main flat portion 32 and a pair of wings 34. Figures 9-10 illustrate the use of wafer 30 in the melt/wipe process for separating tube sections. As shown therein the heated wafer would melt the tube ends and the wings would penetrate into the open space S,S provided at the bight portion of each tube. Wafer 30 could operate in a manner similar to the wafer shown in parent application Serial No. 764,246.

After the four separate tube sections have been formed pairs of tubes would be joined together in the same manner illustrated in Figure 8.

Figure 11 illustrates a further variation of this invention. As shown therein after the bight portion has been melted away and the tube sections are in contact with the flat portion 24 or 32 of the wafer, the tube ends from the resulting four sections assume a generally perpendicular position relative to the flat portion of the wafer. The rate of movement and dimensions may be selected to insure that the exposed tube ends remain in contact with the wafer for a sufficient time so that the melting which takes place includes a melting of the weld seam W. Thus, the weld seam resulting from the prior welding operation is no longer present when the pairs of tubes are later welded together.

Figures 12-14 illustrate an alternative practice of this invention for forming an open space S at the bend of the tube T. As shown therein the tube is laid in the groove of holder 36. As shown in Figure

12 holder 36 includes a pair of pegs or projections 38 disposed on each side of tube T. Tube T is then bent upon itself with the lower portion of the tube in contact with pegs 38 and with the bight of the U-shaped bend being exposed externally of holder 36 as shown in Figure 13. Each tube is then pulled in an inward direction as indicated by the arrow 40 in Figure 12. Upon being inwardly pulled the pegs 38 act to constrict the tube and maintain the bent portion outside of holder 36 while narrowing the thickness in the general area of the pegs 38. This narrowing of thickness creates the open space S. Thus pegs 38 function as structural elements located at the bend for creating the open space. An upper holder member 36A is then mounted to lower holder 36 and a set of thin clamp jaws 40,42 flatten tube T at the portion where tube T emerges from holder 36. As shown in Figure 14 a wafer such as wafer 22 is then used to melt through the bent portions by having the legs 26 pass through the open space of each tube.

Figures 15-17 illustrates the use of pins on a carriage as the structural elements for creating the open space at the bight of the U-shaped bend in the sets of tubes. As shown therein a carriage 44 is mounted on tracks 46 for movement in a horizontal direction with respect to the horizontally oriented bent tubes T. Carriage 44 includes a pair of up-standing mounting members 48 each having a pin or rod 50 extending outwardly in a horizontal plane. Pins or rods 50 would be spaced apart by the distance where the open spaces are to be created at the bent portions of tubes T,T. In practice each tube would be placed in the groove of its respective holder 52 and then the tube would be bent around pins or rod 50 as best illustrated in Figure 16 with each tube then being bent into contact with itself. After each tube T has been bent around its rod 50 the upper clamp jaw 54 is manipulated to flatten each tube with the bight portion extending outwardly from the holders. The physical presence of the rods 50 creates a space at the bight portion of each bent tube. Carriage 44 is then retracted to remove rods 50, thus leaving the open space where the rods had been. After carriage 44 is retracted the carriage is removed and a wafer, such as wafer 22 is used to create four separate tube sections in the manner previously described.

The various practices of this invention are advantageous in that they enable the effective use of bent tubes for obtaining a total containment welding wherein at least one pair of tube sections are connected together. The invention would be ideal for all practical size tubing from 1 mm to 100 mm with the welding apparatus sized to accommodate the particular tube diameter. The invention would be ideal for medical protocols where internal fluids such as gases, liquids or gels must be shut off for

more than, for example, ten seconds.

Preferred embodiments of the invention are disclosed in the claims and also the dependent claims, which should be read as depending not only on the specified claims, but on any other claim and combination thereof. The same is true for the following summary of the invention:

The invention may be summarized as follows:

- 5 1. A method of welding a pair of hollow plastic tubes comprising mounting each tube in the clamp jaws of a holder with each tube bent toward itself to form a U-shaped bend, disposing a structural element generally at the bend to create an open space at the bight of the U-shaped bend externally of the clamp jaws, locating the holders with their bent tubes disposed toward each other, moving a tube section separating member into contact with the bent tubes and through the open space at the bight of each U-shaped bend to create a set of two tube sections from each bent tube, aligning a tube section from one set with a tube section of the other set, and welding the aligned tube sections together.
- 10 2. The method of 1 wherein the tube section separating member is a heated wafer which melts the plastic tubes, and the holders and tubes are aligned during melting of the tubes.
- 15 3. The method of 2 wherein the heated wafer melts the plastic tube in a melt/wipe operation.
- 20 4. The method of 3 wherein the heated wafer has a U-shaped upstream melting section having a pair of legs which pass through the U-shaped bend of the tubes.
- 25 5. The method of 4 wherein each leg includes a sweep member which clears debris out of the melted tubes.
- 30 6. The method of 3 wherein the wafer includes a set of aligned wings which melt through the U-shaped bends of the tubes.
- 35 7. The method of 3 wherein the structural element is a weld seam resulting from the joining together of two tube segments to create each of the plastic tubes.
- 40 8. The method of 7 including mounting each tube in its holder with its weld seam outside the holder pulling back on the tube until the weld seam contacts a spacer bar in the holder, and bending tube over the spacer bar to form the U-shaped bend.
- 45 9. The method of 7 wherein the wafer is maintained in contact with the tube sections a sufficient time to melt the weld seam.
- 50 10. The method of 1 wherein the structural element is a weld seam resulting from the welding together of two tube segments to form each of
- 55

the tubes.

11. The method of 1 wherein the structural element is at least one peg mounted in each holder for constricting the tube after the tube is bent and the tube is pulled in a backward direction.

12. The method of 1 wherein the structural element is a rod over which the tube is bent before being clamped and the rod is then removed to create the open space.

13. A wafer for use in welding a pair of hollow plastic tubes, said wafer comprising a heated member having a lead end and a trailing end, said heated member having a flat main portion, a U-shaped separating portion extending outwardly from said flat main portion at said lead end, and said U-shaped separating portion including a pair of parallel legs extending outwardly from said main portion.

14. The wafer of 13 including a sweep element extending outwardly from each of said legs.

15. The wafer of 14 wherein said sweep element is located centrally across its respective leg.

## Claims

1. A method of welding a pair of hollow plastic tubes comprising mounting each tube in the clamp jaws of a holder with each tube bent toward itself to form a U-shaped bend, disposing a structural element generally at the bend to create an open space at the bight of the U-shaped bend externally of the clamp jaws, locating the holders with their bent tubes disposed toward each other, moving a tube section separating member into contact with the bent tubes and through the open space at the bight of each U-shaped bend to create a set of two tube sections from each bent tube, aligning a tube section from one set with a tube section of the other set, and welding the aligned tube sections together.

2. The method of Claim 1 wherein the tube section separating member is a heated wafer which melts the plastic tubes, and the holders and tubes are aligned during melting of the tubes.

3. The method of Claim 2 wherein the heated wafer melts the plastic tube in a melt/wipe operation,

wherein preferably the heated wafer has a U-shaped upstream melting section having a pair of legs which pass through the U-shaped bend of the tubes, and

wherein preferably each leg includes a sweep member which clears debris out of the melted tubes.

4. The method of Claim 2 wherein the heated wafer melts the plastic tube in a melt/wipe operation, and

wherein preferably the wafer includes a set of aligned wings which melt through the U-shaped bends of the tubes.

5. The method of Claim 2 wherein the heated wafer melts the plastic tube in a melt/wipe operation,

wherein preferably the structural element is a weld seam resulting from the joining together of two tube segments to create each of the plastic tubes, and preferably

including mounting each tube in its holder with its weld seam outside the holder pulling back on the tube until the weld seam contacts a spacer bar in the holder, and bending tube over the spacer bar to form the U-shaped bend.

6. The method of Claim 2 wherein the heated wafer melts the plastic tube in a melt/wipe operation,

wherein preferably the structural element is a weld seam resulting from the joining together of two tube segments to create each of the plastic tubes, and

wherein preferably the wafer is maintained in contact with the tube sections a sufficient time to melt the weld seam.

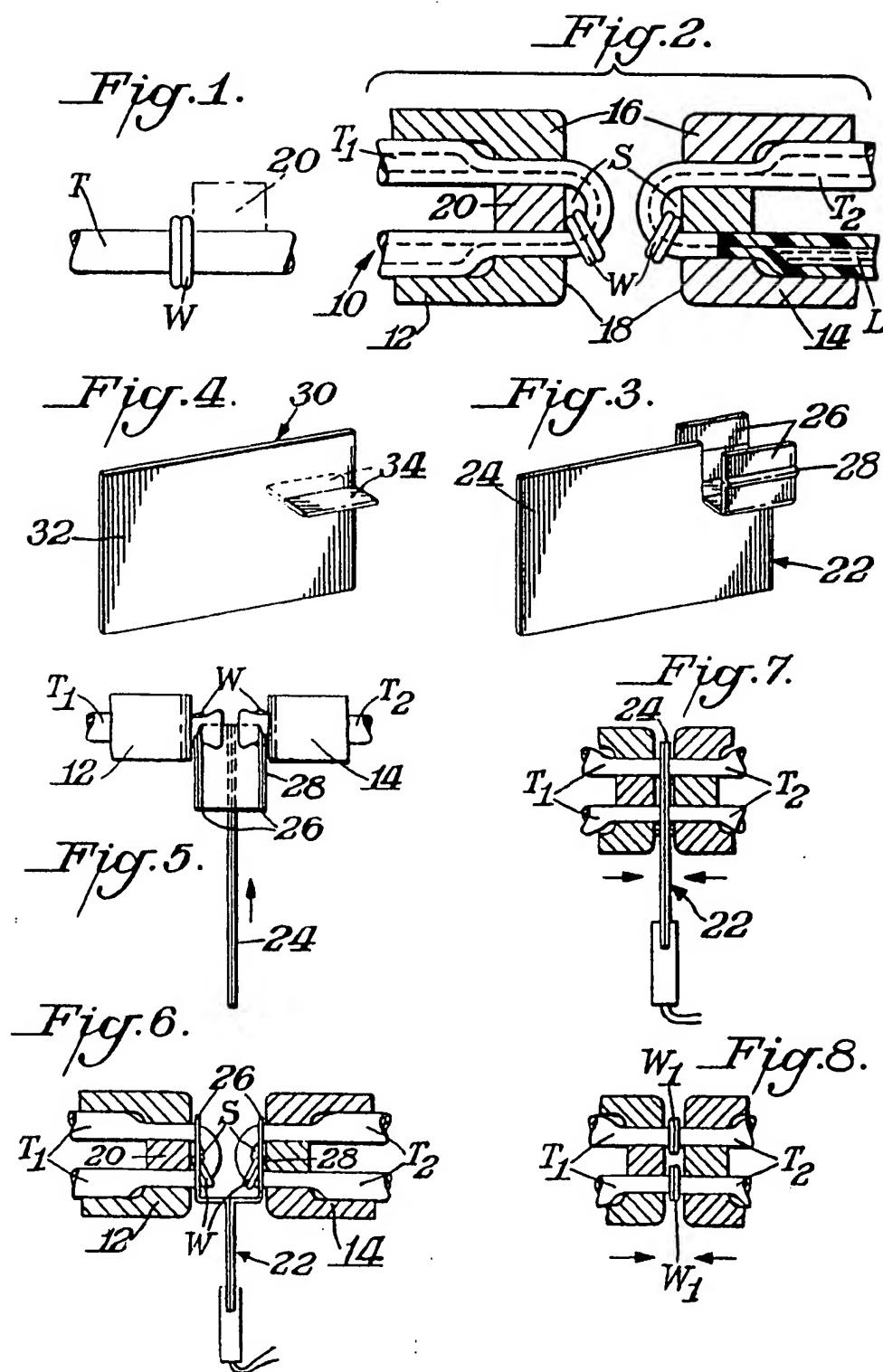
7. The method of Claim 1 wherein the structural element is at least one peg mounted in each holder for constricting the tube after the tube is bent and the tube is pulled in a backward direction.

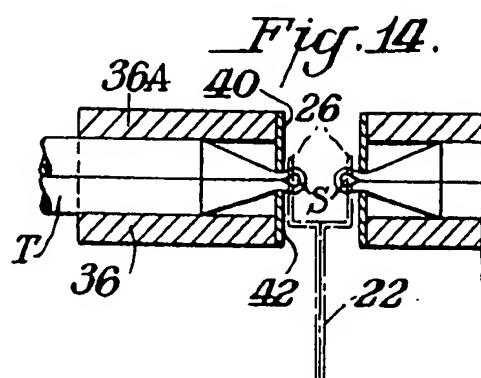
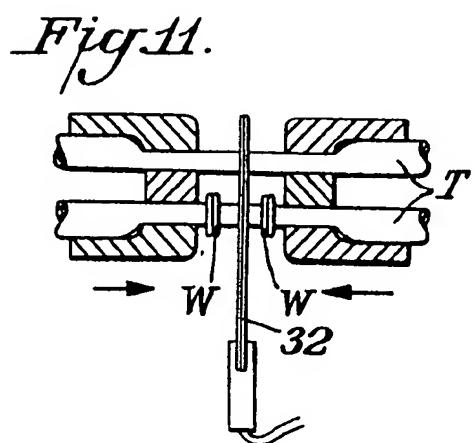
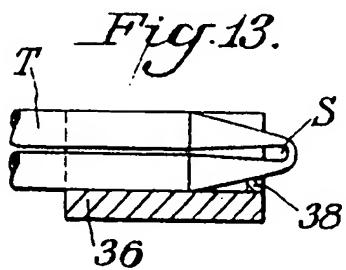
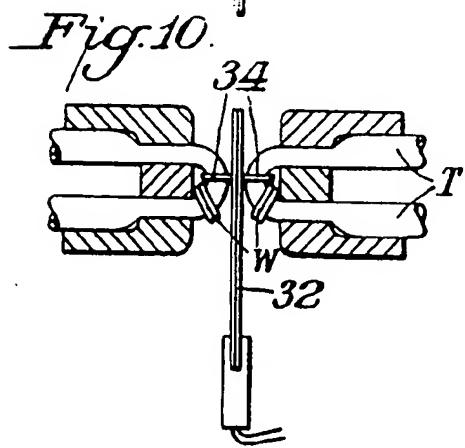
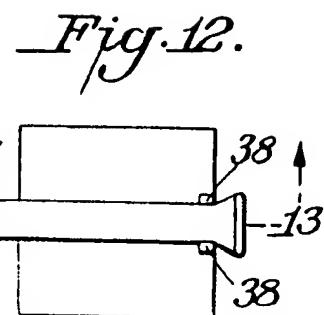
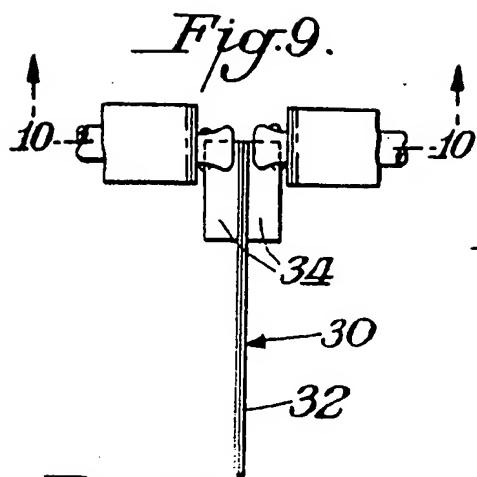
8. The method of Claim 1 wherein the structural element is a rod over which the tube is bent before being clamped and the rod is then removed to create the open space.

9. A wafer for use in welding a pair of hollow plastic tubes, said wafer comprising a heated member having a lead end and a trailing end, said heated member having a flat main portion, a U-shaped separating portion extending outwardly from said flat main portion at said lead end, and said U-shaped separating portion including a pair of parallel legs extending outwardly from said main portion.

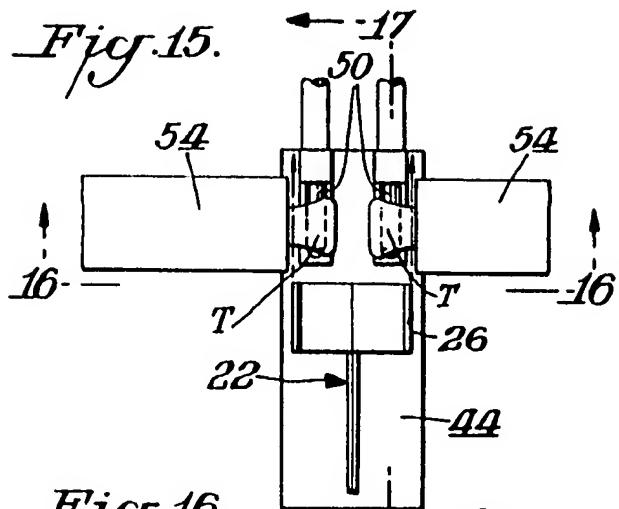
10. The wafer of Claim 9 including a sweep element extending outwardly from each of said legs, and

wherein preferably said sweep element is located centrally across its respective leg.

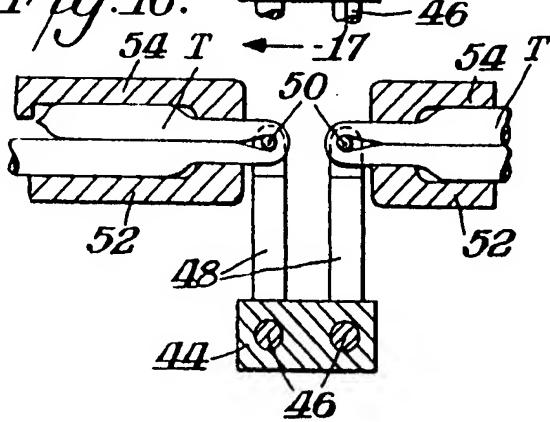




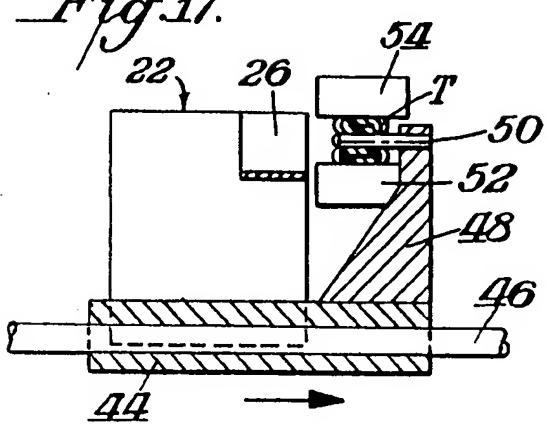
*Fig.15.*



*Fig.16.*



*Fig.17.*





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EUROPEAN SEARCH REPORT

Application Number  
EP 93 11 0301

DOCUMENTS CONSIDERED TO BE RELEVANT			CLASSIFICATION OF THE APPLICATION (Int.Cl.)						
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim							
D, X	EP-A-0 483 478 (DENCO INC.) * figures 11-17 *	1, 2, 4, 9	B29C65/20 A61M39/00 //B29L23:22						
P, X	EP-A-0 515 811 (DENCO INC.) * figures 8, 9, 15 *	1							
P, A	EP-A-0 508 373 (DENCO INC.) * claim 1; figure 4 *	8							
D, A	US-A-4 753 697 (J.B. SHAPOSKA) * figures 14, 15, 17 *	1							
A	US-A-2 945 532 (E. DE FILIPPO) * figure 3 *	10							
			TECHNICAL FIELDS SEARCHED (Int.Cl.)						
			B29C A61M						
<p>The present search report has been drawn up for all claims</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 33%;">Place of search</td> <td style="width: 33%;">Date of completion of the search</td> <td style="width: 33%;">Examiner</td> </tr> <tr> <td>THE HAGUE</td> <td>24 November 1993</td> <td>Cordenier, J</td> </tr> </table>				Place of search	Date of completion of the search	Examiner	THE HAGUE	24 November 1993	Cordenier, J
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CATEGORY OF CITED DOCUMENTS		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document							
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